Rhode Island Department of Health

INSTITUTIONAL REVIEW BOARD

FOR THE

PROTECTION OF HUMAN SUBJECTS

Guidance for Submitting Applications to the IRB:

Procedures
Forms
Contacts

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For information contact:

John P. Fulton, PhD, Chair
Telephone (401) 222-1172
Fax (401) 222-3551
E-mail: John.Fulton@health.ri.gov

Leonard Green, MPS, Vice-Chair
Telephone (401) 222-7841
Fax (401) 222-4393
E-mail: LennyG@doh.state.ri.us

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JURISDICTION OF THE HEALTH INSTITUTIONAL REVIEW BOARD

The Rhode Island Department of Health (HEALTH) operates an Institutional Review Board (IRB) that reviews proposals for research on human subjects under a Federal Wide Assurance (FWA). The HEALTH IRB's jurisdiction extends to all research proposals that involve HEALTH staff, data, or other resources, specifically where a proposed project has:

- An employee* of the Department serving as Principal Investigator, Co-Investigator or in any role with scientific responsibility in the research project, whether paid or in-kind.
- An employee* of the Department of Health is funded under the grant, contract, cooperative agreement, or other award supporting the research project.
- An employee* of the Department engages directly in recruitment, data collection, or intervention with human research subjects or in any other activity requiring informed consent or assent or for which informed consent is usually required but has been waived as allowed in federal human subjects protection regulations.
- The Department provides confidential data, in which an individual is identified directly or indirectly, to the project.
- The Department provides any financial or in-kind support for the performance of the research project.
- An employee* of the Department will be an author of a manuscript resulting from the research that will be submitted for publication and that will include the employee's affiliation with the Department.

*{*For the purposes of this policy, employees of the Rhode Island Department of Health are (1) full-time and part-time employees in the state personnel system and (2) contract employees.*

PROCEDURES FOR SUBMITTING PROPOSALS TO THE HEALTH IRB

Proposals that may be exempt from IRB Review
If it is determined that human subjects are involved, the Principal Investigator shall consult with the Chair of the IRB to make a preliminary determination of whether the research involved is exempt from IRB review. In situations where the Principal Investigator is a student, the student's faculty sponsor at the institution in which the student is enrolled shall also consult in the decision regarding exempt status. Where it is clear that the project is in the "exempt" category, the research work may proceed *only after* determination of exempt status by the Chair of the IRB. If the IRB Chair cannot assign the status of the project based on preliminary discussions with the Principal Investigator and/or faculty sponsor, the Principal Investigator must make a formal request for IRB review and submit the following information:

1. A letter from the Principal Investigator stating why the exemption should be granted and citing which of the six published reasons for exemption applies (see Appendix A, "Research Exempt from IRB Review"). Where the Principal Investigator is a student, the letter should either be written by or endorsed by the student's faculty sponsor.

2. A completed "Proposal Abstract Cover Sheet."

3. Two copies of the research proposal, including any informed consent forms to be used. Include copies of survey forms, questionnaires, or interview questions, if applicable.

4. An "Assurance of the Principal Investigator" form. If the Principal Investigator is a student, the student's faculty sponsor should sign the form.

5. If the research involves a cooperating agency, institution, school district, or other organization, a letter of agreement to participate in the research, written on official letterhead, is also required. Research that is to be conducted in foreign countries requires a letter of agreement from an appropriate official or cooperating institution.

Proposals that are not exempt from IRB Review
If the proposal qualifies for expedited or full IRB review (see Appendices X and Y), the Principal Investigator must submit two (2) copies of the complete research proposal*, less any appended material not necessary to a full understanding of the project, plus two (2) copies of a package containing the following:

1. "Proposal Abstract Cover Sheet"

2. A completed "Application for Review"

3. A signed "Assurance of the Principal Investigator"

4. An "Informed Consent" form, if applicable

5. If the research involves a cooperating agency, institution, school district, or other organization, a letter of agreement to participate in the research, written of official letterhead, is required. Research that is to be conducted in foreign countries requires a letter of agreement from an appropriate official or cooperating institution.

*If the proposal is part of a thesis, dissertation, or sponsored research grant proposal, two (2) copies of that proposal should also be submitted.

Mail or deliver all application materials to:

John P. Fulton, PhD, Chair
Institutional Review Board
Room 403
Rhode Island Department of Health
3 Capitol Hill
Providence, RI 02908-5097

CONFIDENTIALITY, PRIVACY AND RESEARCH RISK

Many research proposals submitted to the HEALTH Institutional Review Board involve use of personally identifiable confidential information in the Department's databases, with no intent to contact the individuals whose information is being used. These proposals may be eligible for exemption from informed consent requirements or review under the expedited procedure. Such proposals should address the following issues in their IRB submissions:

- Determine whether the proposed use of the data is research on human subjects as defined in the federal regulations governing human subjects protection. (See Appendix A);
- Specify the risks and benefits of participating in the research for the human subjects. There are often no direct benefits to individuals whose confidential data is accessed. Risks may often include inadvertent and purposeful release of confidential data on an individual. Such release may occur through release of sufficient descriptive information as to allow identification, even when no identifiers are released.
- Minimize the risks to human subjects in the design and conduct of the research. For use of existing data, this means that:
  - The minimum amount of confidential information is requested that is necessary to perform the research.
  - The information is accessible to and handled by the minimum number of personnel possible.
  - Identifiers are removed from the database or the database is returned to the owner as soon as no longer needed.
  - Data that are published or otherwise released are aggregated so that no individual can be identified either directly or indirectly through knowledge of non-confidential data items.
- Specify measures to protect data when on computers and when stored on electronic media. Also describe any data linkages that would result in anonymous data becoming identifiable to an individual.
- If any contact is proposed with an individual identified through access to a HEALTH database, the issues of informed consent become relevant, and all protocols and forms must be reviewed in addition to measures to protect confidentiality.

THE INFORMED CONSENT PROCESS AND GENERAL REQUIREMENTS FOR THE INFORMED CONSENT STATEMENT

1. **Informed consent should be considered a process that may require continual review; it is not just a legal document.**

2. Informed consent must be obtained only under such circumstances that provide the prospective subject, or the subject's representative, sufficient opportunity to consider participation in the research project and where the possibility of coercion or undue influences is minimized.

3. The Informed Consent Statement

    a. Must be written in language understandable to the subject or representative;

    b. Shall not contain any language by which the subject waives any of his or her rights;

    c. Shall not contain any language that releases the principal investigator or the sponsoring agency from liability for negligence;

    d. Should include a statement such as, "you are over 18 years of age," if appropriate.

4. The Informed Consent Statement should follow the format and outline given on the next page, as appropriate. When the subject is a minor and the parent or guardian's consent is sought, space for the parent or guardian's signature should be provided. If the subject is an adult requiring guardian consent, space for the guardian's signature should be provided. Alternatively, where it is necessary to separate the consent of the parent/guardian from the assent of the minor or non-consenting adult, separate forms should be used for each.

5. Two copies of the Informed Consent statement must be signed; one copy is to be retained by the individual (or his/her representative/guardian), and one copy is to be kept by the principal investigator. (NOTE: the signature page may not be completely separated from the text of the informed consent.)

N.B. For further guidance, see the "Informed Consent Information" section on the OHRP website.

SAMPLE INFORMED CONSENT FORM

Title of Project _____

Introductory section should begin with words to this effect:
You have been asked to take part in a research project described below. The researcher will explain the project to you in detail. You should feel free to ask questions. If you have more questions later, {P.I.}, the person mainly responsible for this study, { Phone }, will discuss them with you. You must be at least 18 years old to be in this research project (if appropriate).

Description of the project:
You have been asked to take part in the study that {here describe the nature of the study and the purpose of the research}.

What will be done:
If you decide to take part in this study here is what will happen: {explanation of what will happen to the subject; how long the subject will be involved in the study; and state what portions, if any, are considered experimental. Explain alternative procedures, if any}.

Risks or discomfort:
{Explain any risks or discomfort that might reasonably be expected to happen. If there are no risks or discomforts, state that here}.

Benefits of this study:
{Describe benefits to the subject, or to others, of this study. If of no direct benefit to the subject, include a sentence to the following effect:} Although there will be no direct benefit to you for taking part in this study, the researcher may learn more about { }. (NOTE: payment given to the subject for participation in the study is not a benefit, it is a recruitment incentive.)

Confidentiality:
{Describe the way confidentiality of records identifying the subject will be maintained. Use words to the following effect, if appropriate:} Your part in this study is confidential. No information will be released that identifies you by name. All records will {describe how records are to be maintained}. {Or, if the study involves information that legally must be reported to government agencies, then include the following:} My part in this study is confidential within legal limits. The researchers and the sponsoring agency will protect your privacy, unless they are required by law to report information to city, state or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify you by name. All records will be {describe how they are to be maintained}.{Alternatively, if the study is anonymous, then this should be stated here. Indicate to the subject how anonymity will be preserved.}

In case there is any injury to the subject: (If applicable)
{Explain whether any medical or other treatment is available if injury occurs, and who to contact; use words to this effect:} If this study causes you any injury, medical treatment will be provided to you through { }, and this treatment will be paid for by { }. To report any injury that happens because you agreed to be in this study, you should write or call { }.

Decision to quit at any time:
{Use words to the following effect:} The decision to take part in this study is up to you. You do not have to participate. If you decide to take part in the study, you may quit at any time. Whatever you decide will in no way {penalize you} {affect your benefits, medical care}{etc.} {insert appropriate language}. If you wish to quit, you simply inform {name and phone number of principal investigator} of your decision.

Rights and Complaints:
{Use words to the following effect:} If you have any questions later about your rights as a participant in this research, or if you are not satisfied with the way this study is performed, you may speak with {P.I.'s Name} or with {name and phone of individual}, anonymously, if you choose. In addition, you may contact { }, who is the Administrator of the Institutional Review Board of the Rhode Island Department of Health, at { }.

You have read the Consent Form. Your questions have been answered. Your signature on this form means that you understand the information and you agree to participate in this study.

_____	_____
Signature of Participant	Signature of Researcher
_____	_____
Typed/printed Name	Typed/printed name
_____	_____
Date	Date

CONSENT FORM
(*Name of Project*)

TEAR OFF AND KEEP THIS FORM FOR YOURSELF

Dear Participant:

1. You have been asked to take part in the research project described below. If you have any questions, please feel free to call (PI*, phone number*), the person mainly responsible for this study.
2. The purpose of this study is to (*state purpose*). Responses to these items will be (*state how responses will be collected and how confidentiality will be maintained)*.
3. **YOU MUST BE AT LEAST 18 YEARS OLD** to be in this research project or to consent to your child's participation.
4. If you decide to take part in this study, your participation will involve (describe procedures) pertaining to (*state appropriate information*).
5. The possible risks or discomforts of the study are minimal, although you may feel some embarrassment answering questions about private matters (*delete last phrase if it is not appropriate for your project*).
6. Although there are no direct benefits of the study, your answers will help increase the knowledge regarding (*state appropriate information*).
7. Your part in this study is confidential. That means that your answers to all questions are private. No one outside the project can know if you participated in this study or know any information about your participation. Scientific reports will be based on group data and will not identify you or any individual as being in this project.
8. The decision to participate in this research project is up to you. You do not have to participate and you may quit at any time.
9. Participation in this study is not expected to be harmful or injurious to you. However, if this study causes you any injury, you should call the "IRB Administrator" at the Rhode Island Department of Health, {phone #}.

If you have any more questions or concerns about this study, you may contact _____at_____.
You are at least 18 years old. You have read the consent form and your questions have been answered to your satisfaction. Your filling out the survey implies your consent to participate in this study.
If these questions are upsetting and you want to talk, please use the phone numbers below: (*appropriate in cases where questions are of a sensitive nature*):

(*Names and phone numbers of resources available, e.g., Counseling Center, Women's Resource Center, AA, etc.*).

Thank you, (*Name of Investigator*)

ANNUAL REVIEW OF CONTINUING RESEARCH

The Code of Federal Regulations empowers the Institutional Review Board (IRB) to "conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, and to observe or have a third party observe the consent process and the research." (45 CFR 46.109(e)).

Approved projects are assigned a monitoring date. It is the policy of the HEALTH IRB that all investigators are sent a monitoring form in advance of that date, and that the form must be completed and returned to the HEALTH IRB ten days before the designated date. In addition, investigators will be asked to submit (1) a copy of the project's current informed consent document, if appropriate, and (2) a summary progress report for the project covering the period since the last review by the HEALTH IRB, including any recent literature, findings, or information that has become available concerning risks associated with the research. The IRB will review these documents to ensure that your research protocol continues to be in compliance with federal and state regulations**. This policy notwithstanding, it is the responsibility of the investigator to ensure that the investigator's project remains compliant in the continuing review requirement.**

Continuing research must be monitored and approved for continued IRB approval. If you do not respond to our request for review within the specified time frame, your project will no longer have IRB approval.

Please refer also to the Rhode Island Department of Health IRB Operating Policies and Procedures, Section XII. Procedures for Continuing Review.

Rhode Island Department of Health IRB Members

CHAIR

John P. Fulton, PhD
Division of Disease Prevention and Control
R.I. Department of Health
3 Capitol Hill
Providence, RI 02908
Voice: 222-1172
Fax: 222-3551
E-mail: John.Fulton@health.ri.gov

VICE-CHAIR

Leonard B. Green, MPS
Office of Vital Records
R.I. Department of Health
3 Capitol Hill
Providence, R.I. 02908
Voice: 222-7841
Fax: 222-4393
E-mail: lennyg@doh.state.ri.us

FULL BOARD MEMBERS

Utpala Bandyopadhyay, MD, MPH
Division of Disease Prevention and Control
R.I. Department of Health
3 Capitol Hill
Providence, RI 02908
Voice: 222-2432
Fax: 222-2488
E-mail: utpalab@doh.state.ri.us

Jay S. Buechner, PhD
Office of Health Statistics
R.I. Department of Health
3 Capitol Hill
Providence, RI 02908
Voice: 222-2550
Fax: 273-4350
E-mail: jayb@doh.state.ri.us

Bruce McIntyre, JD, Attorney
Board of Medical Licensure and Discipline
R.I. Department of Health
3 Capitol Hill
Providence, RI 02908
Voice: 222-7890
Fax: 222-2158
E-mail: brucem@doh.state.ri.us

Lynn Pasquerella, PhD
Vice Provost
Department of Philosophy
Research Office
Kingston, RI 02881
Voice: 874-2223
E-mail: paski@URI.edu

Elizabeth Shelov, MPH, MSSW
Division of Health Services Regulation
R.I. Department of Health
3 Capitol Hill
Providence, RI 02908
Voice: 222-1039
Fax: 222-3017
E-mail: lizs@doh.state.ri.us

Vivian Weisman, MSW
Rhode Island Parent Information Network
175 Main Street
Pawtucket, RI 02860
Voice: 727-4144 x 126
Fax: 727-4040
Weisman@ripin.org

ALTERNATE MEMBERS

Ewa King, Ph.D.
Division of Laboratories
R.I. Department of Health
50 Orms Street
Providence, RI 02906
Voice: 222-5555
E-mail: Ewa.King@health.ri.gov

Sharon Marable, MD, MPH
Division of Disease Prevention and Control
R.I. Department of Health
3 Capitol Hill
Providence, RI 02908
Voice: 222-5353
Fax: 222-4415
E-mail: sharonm@doh.state.ri.us

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FOR ADDITIONAL INFORMATION

For general information involving human subjects protection, visit the website for the Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services:

http://www.hhs.gov/ohrp

For documents relating to human subjects protection, including -

- The "Belmont Report"
- Regulations for the Protection of Human Research Subjects (45 CFR 46)
- Informed Consent Information

visit the following website:
http://www.hhs.gov/ohrp/policy/index/html

and for the Institutional Review Board Guidebook, visit the following website:

http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

For guidance with human subjects protection issues in public health, see the human subjects protection website at the Centers for Disease Control and Prevention:

http://www.cdc.gov/od/ads

For information on federal certificates of confidentiality, which protect confidential information collected on research subjects from access through most federal, state, and local legal actions, such as subpoenas, see the following website:

http://www.hhs.gov/ohrp/policy/index/html

For Rhode Island's Confidentiality of Healthcare Communications and Information Act (Rhode Island General Laws Chapter 5-37.3) and specifically for requirements relating to the release of medical records (Section 5-37.3-4(d)) see:

http://www.rilin.state.ri.us/Statutes/TITLE5/5-37.3/INDEX.HTM